infringe the patent.[2] Patstats, U.S. Patent Litigation Statistics, University of Houston Law Center, available at http://www.patstats.org/2003.html (detailing that, in 2003, of 339 infringement decisions, the patent was found to not be infringed 255 times, 75%).

Although one comprehensive analysis performed in the late 90's determined that patent holders were successful in asserting their patents against accused infringers 58% of the time, more recent data suggests that the exclusionary power of patents in general is declining. Kimberly A. Moore, *Judges, Juries, and Patent Cases – An Empirical Peek Inside the Black Box*, 99 Mich. L. Rev. 365, 385 (Nov. 2000); Patstats, U.S. Patent Litigation Statistics, University of Houston Law Center, available at http://www.patstats.org/2003.html.

Since roughly half of all asserted patents end up having no exclusionary power whatsoever, it was improper for the Court of Appeals to assume that Schering's patent would have complete exclusionary power with respect to all generic products throughout its full term. Such an assumption was no more justified than assuming the patent will have no exclusionary power with respect to any product.

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[2] The Court of Appeals manifested an incorrect understanding of patent law when it stated that "[b]y virtue of its '743 patent, Schering obtained the legal right to exclude Upsher and ESI from the market until they proved either that the '743 patent was invalid or that their products . . . did not infringe Schering's patent." Id. at 1066. In fact, although the burden of proving a patent invalid does lie with an accused infringer, the patent holder has the burden of proving infringement. An accused infringer need not prove it does not infringe a patent in order to be outside the patent's right to exclude.

B. When a Patent Holder Allows a Product to Be Freely Sold Prior to Expiration of a Patent, the Exclusionary Power of that Patent With Respect to that Product Ends on the Date the Product Was Allowed to be Freely Sold.

Beyond general empirical analysis, there are several ways to determine what the exclusionary power of a patent is with respect to a specific product. First, and most obviously, a court can make a final determination regarding whether the patent has the power to exclude the product during the term of the patent. However, completed patent litigation is not the only way for the exclusionary power of a patent to be determined.

If a patent holder and a manufacturer of a product come to an agreement regarding the effect of a patent on that product, another way to determine the exclusionary power of the patent with respect to that product is to identify what the parties negotiated it to be in the absence of a payment from the patentee. For example, if a patent holder and alleged infringer settle a dispute between them regarding whether a specific patent has the power to exclude a specific product for the full term of the patent and the terms of that settlement allow the product to be freely sold without payment of any license fees or other consideration to the patent holder, then the exclusionary power of the patent with respect to that product ends as of the date the product is allowed to be freely sold.

The Court of Appeals seems to think that the exclusionary power of a patent can only be absolute; either zero or full term. However, such an argument fails to recognize that patent rights are fraught with inherent uncertainty and that it is economically efficient to allow patent owners

to recognize through private arrangements that their patents have the power to exclude a certain product for an amount of time less than the full term of the patent. When such a deal is struck, the exclusionary power of the patent is determined by analyzing the amount of exclusion achieved by the patent holder through the negotiation. Therefore, it is entirely possible, and actually quite frequently the case, that the exclusionary power of a patent with respect to a specific product is less than its full term.

For example, in this case the agreement between Schering and Upsher-Smith ("Upsher") implicitly had three distinct and separate economic aspects. The first economic aspect of the agreement was that Schering permitted Upsher to sell its generic K-Dur product prior to the asserted patent's expiration date without any requirement that Upsher make any payment or give any consideration to Schering other than a promise to abstain from selling the generic K-Dur product prior to that date. That agreed-to date of entry, referred to herein as T, is the most precise measure of the asserted patent's exclusionary power with respect to Upsher's product, as that was a date negotiated by parties who were, at the time of negotiation, adversaries regarding the patent's power to exclude the generic K-Dur product. In effect, T was a specifically tailored expiration date for the patent with respect to Upsher's product.

The second economic aspect of the agreement was that Schering paid Upsher some amount less than $60M for an additional promise to not sell generic K-Dur between the specifically tailored patent expiration date, T, and September 2001. This additional delay was not within the exclusionary power of the patent. Rather, it began on the day the exclusionary power of the patent ended and

extended the total amount of time Upsher delayed its sale of the generic K-Dur product.

Had Schering not paid Upsher for any additional delay, then T would be properly identified as being September 2001, or, had Upsher instead paid Schering consideration for Schering's allowance of the generic K-Dur product to be sold prior to the patent's expiration, then T would have been some date after September 2001. But, since Schering compensated Upsher for its delay with a combination of cash and a waiver of the exclusionary power of the patent, only a portion of the delay can be attributed to the patent's exclusionary power. This is why T must have been, under the terms of this agreement, some date prior to September 2001.

The final aspect of the agreement was that Schering paid Upsher some amount less than $60M for a license to Niacor-SR. The combination of the amount paid to Upsher for the additional delay and the amount paid for the license to Niacor-SR equaled the total $60M under the agreement. Set forth below in Figure 1 is a chart identifying these three aspects of the agreement and the consideration exchanged by the parties to achieve those aspects.

Aspect	Consideration Given by Schering	Consideration Given by Upsher
1. Exclusionary Power of Schering's Patent	Promise to Not Assert Patent Against Generic K-Dur after Date T (T is before Sept. 2001)	Promise to Not Produce Generic K-Dur Before Date T
2. Additional Exclusion	$ X (where $0 < X < $60M)	Promise to Not Produce Generic K-Dur Between Date T and September 2001
3. Niacor-SR License	$ Y (where Y = $60M – X)	License to Niacor-SR

FIGURE 1: Economic Aspects of Schering – Upsher Settlement Agreement

Admittedly, the negotiations and text of the agreement obfuscated these economic aspects. Instead of delineating each economic aspect and dealing with them separately, Respondents combined the considerations that were of like form. The consideration given by Schering for the second and third aspect of the agreement was cash, and therefore they were merged. The consideration given by Upsher for the first and second aspect of the agreement was combined into a single promise to not sell generic K-Dur prior to September 2001. Set forth below in Figure 2 is the same chart as set forth above in Figure 1, except that the considerations merged through the text of the agreement are shown as being merged in the chart.

<table>
<tr><th>Aspect</th><th>Consideration Given by Schering</th><th>Consideration Given by Upsher</th></tr>
<tr><td>1. Exclusionary Power of Schering's Patent</td><td>Promise to Not Assert Patent Against Generic K-Dur after Date T
(T is before Sept. 2001)</td><td rowspan="2">Promise to Not Produce Generic K-Dur Before September 2001</td></tr>
<tr><td>2. Additional Exclusion</td><td rowspan="2">$60M</td></tr>
<tr><td>3. Niacor-SR License</td><td>License to Niacor-SR</td></tr>
</table>

FIGURE 2: Economic Aspects of Schering – Upsher Settlement Agreement as Obfuscated by the Agreement Provisions

This merging of like-consideration is understandable, as it is easier to negotiate and draft two forms of consideration flowing from each party to the other, rather than three. However, that does not change the economic realities of the deal. Since a portion of Upsher's delay was compensated for by part of Schering's $60M, only the remaining portion of Upsher's delay was due to the power of the patent to exclude generic K-Dur. Therefore, the exclusionary power of the patent in this case with respect to Upsher's generic product was determined by the parties, whether they realized it or not at the time, to be some date prior to September 2001.

Although this is not a precise determination of the exclusionary effect of the patent, resolution of antitrust issues relating to the exclusionary power of a patent does not necessarily require a precise determination. As in this case,

antitrust analysis can be appropriately applied merely by identifying the bounds of the exclusionary effect of a patent. Therefore, it is sufficient to recognize that the parties determined, through their negotiations, that Schering's patent did not have the power to exclude Upsher's generic K-Dur product after some date prior to September 2001.

Similarly, the exclusionary effect of Schering's patent with respect to ESI Lederle's ("ESI") generic product can be determined by reviewing the Schering - ESI agreement, which is easier to analyze because it did not include the third aspect present in the Schering – Upsher agreement. In the Schering – ESI agreement, Schering allowed the ESI generic product to enter the market prior to expiration of its patent and also paid ESI $10M above and beyond its litigation costs. Since there was no other justification for that additional payment, it could only have been in exchange for additional delay of entry of ESI's generic product into the market. Therefore, the parties determined, through their agreement, that Schering's patent did not have the power to exclude ESI's generic product after some date prior to January 1, 2004, referred to herein as S. Set forth below in Figure 3 is a chart identifying these aspects of the Schering – ESI agreement and the consideration exchanged by the parties to achieve those aspects.

Aspect	Consideration Given by Schering	Consideration Given by ESI
1. Exclusionary Power of Schering's Patent	Promise to Not Assert Patent Against Generic K-Dur after Date S (S is before January 1, 2004)	Promise to Not Produce Generic K-Dur before Date S
2. Additional Exclusion	$10M	Promise to Not Produce Generic K-Dur Between Date S and January 2004

FIGURE 3: Economic Aspects of Schering – ESI Settlement Agreement

The Court of Appeals failure to adopt this reasoning led it to make the erroneous decision that any settlement of patent litigation is pro-competitive so long as the accused infringing product is allowed to enter the market any time before expiration of the asserted patent. This decision, if left uncorrected, will cause significant harm to the American people by permitting anti-competitive settlements of patent infringement litigation whereby potential competitors, instead of competing, take a share of the monopoly profits that can be maintained if they stay off the market. Unquestionably, such agreements are very good for the parties, and perhaps even the court system, which will have the burden placed on it lessened by the termination of patent infringement cases, but it is also just as clear to see how such agreements spell nothing but disaster for our competition-based economy and the American consumer.

II. THE COURT OF APPEALS IGNORED THIS COURT'S PRECEDENT BY EXEMPTING A SIGNIFICANT PORTION OF PATENT SETTLEMENTS FROM ANTITRUST LAW.

This Court has recognized that discouraging anticompetitive settlements of patent infringement cases has, in itself, a pro-competitive effect. Accused infringers who prove a patent invalid perform an important public service by correcting the PTO's errors on their own nickel. *See Lear v. Adkins*, 395 U.S. 653, 670 (1969) (explaining that if those "with economic incentive to challenge the patentability of an inventor's discovery" do not do so, "the public may continually be required to pay tribute to would be monopolists without need or justification"); *Pope Mfng. Co. v. Gormully*, 144 U.S. 224, 234 (1892) ("[i]t is as important to the public that competition should not be repressed by worthless patents as that the patentee of a really valuable invention should be protected in his monopoly"). Even those who try but fail to prove a patent invalid perform a public service by narrowing uncertainty as to the patent's validity, thus encouraging others to respect it. *Kloster Speedsteel AB v. Crucible, Inc.*, 793 F.2d 1565, 1581 (Fed. Cir. 1986).

Similarly, accused infringers who do not raise invalidity challenges to an asserted patent, but instead raise substantial noninfringement defenses also aid competition because their efforts lead to a judicial opinion declaring the patent's metes and bounds, on which the public may rely. Determining the true scope of a patent is accomplished by the courts through a process called claim construction, which is often difficult, as evidenced by the fact that the U.S. Court of Appeals for the Federal Circuit reverses over 30% of district court claim constructions. *See*

Christian Chu, *Empirical Analysis of the Federal Circuit's Claim Construction Trends*, 16 Berkeley Tech. L.J. 1075 (2001); *see also* Kimberly A. Moore, *Are District Court Judges Equipped to Resolve Patent Cases?*, 15 Harv. J.L. & Tech. 1 (2001). As such, a party that litigates the scope of a patent through the stage of claim construction aids the public in determining what the patent covers and, more importantly, what it does not. These significant pro-competitive effects that result from the discouragement of anti-competitive settlements went unrecognized by the Court of Appeals in this case.

Further, the Court of Appeals failed to recognize that application of sound antitrust law and policy comports with the policies implemented in the Hatch-Waxman Act. The entire point of Hatch-Waxman was to encourage and protect competition in the pharmaceutical industry, which it did in two principal ways: (i) making it easier for competition to already available products to be introduced; and (ii) encouraging new innovative products to be brought to market by strengthening patent rights. *See* H. Rep. No. 98-857(I). Unfortunately, pharmaceutical companies, both brand and generic, have been able to circumvent the pro-competitive intent of Hatch-Waxman because it is "littered with loopholes." Lara J. Glasgow, *Stretching the Limits of Intellectual Property Rights: Has the Pharmaceutical Industry Gone Too Far?*, 41 IDEA 227 (2001). The use of patent settlement agreements to fashion a sharing of monopoly profits made by one of them instead of competing with one another in the marketplace, such as occurred in this case, is but one example of how pharmaceutical companies are attempting to circumvent Hatch-Waxman. By condoning net-anticompetitive gaming of the Hatch-Waxman regime

through patent infringement litigation settlement agreements, the Court of Appeals' decision will frustrate, not promote, Hatch-Waxman's goals.

CONCLUSION

For the foregoing reasons, this Court should grant the petition for a writ of *certiorari*.

Respectfully submitted,

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September 30, 2005

Supreme Court, U.S.
FILED
SEP 30 2005
OFFICE OF THE CLERK

No. 05-273

IN THE

Supreme Court of the United States

FEDERAL TRADE COMMISSION,

Petitioner,

v.

SCHERING-PLOUGH CORPORATION, ET AL.,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

MOTION AND BRIEF OF REPRESENTATIVE HENRY A. WAXMAN AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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MOTION OF REPRESENTATIVE HENRY A. WAXMAN FOR LEAVE TO FILE BRIEF AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

Representative Henry A. Waxman respectfully moves for leave to file a brief as *amicus curiae* in support of the petitioner. Counsel for respondents Schering-Plough Corporation and Upsher-Smith Laboratories, Inc., have declined to consent to the filing of the brief, necessitating the filing of this motion.

Representative Waxman is a member of the United States House of Representatives representing California's 30th Congressional District. Representative Waxman has served in the House since 1974 and is currently Ranking Minority Member of the House Committee on Government Reform, which has investigative authority over all government agencies and areas of federal policy.

Representative Waxman has long been a leader on health issues, including universal health insurance, Medicare and Medicaid coverage, tobacco, AIDS, nursing home quality standards, women's health research and reproductive rights, and the availability and cost of prescription drugs. Most significantly for purposes of this case, Representative Waxman was one of two principal named sponsors of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, more commonly referred to as the Hatch-Waxman Act. That legislation, and the policies it reflects, is directly at issue in this case. Representative Waxman was also a leading advocate of the reforms to the Hatch-Waxman Act included in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066.

Representative Waxman seeks leave to file this brief because he believes the decision of the U.S. Court of Appeals for the Eleventh Circuit in this case stands as a significant obstacle to the fulfillment of the important public policies

embodied in the Hatch-Waxman Act and its 2003 amendments, both of which sought to speed the introduction of generic competitors to name-brand drugs, not to facilitate anti-competitive agreements between pharmaceutical companies to keep generics off the market. Representative Waxman seeks to provide the Court with additional information about the policies underlying these important pieces of legislation to assist it in appreciating the significance of this case.

Representative Waxman therefore respectfully asks that he be granted leave to file the accompanying brief as *amicus curiae* in support of the petitioner.

Respectfully submitted,

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September 30, 2005

QUESTION PRESENTED

Whether the Eleventh Circuit's approval of anti-competitive settlement agreements between generic and name-brand drug manufacturers can be squared with the policies of the Hatch-Waxman Act and its 2003 amendments.

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INTEREST OF *AMICUS CURIAE*

As set forth in detail in the accompanying motion for leave to file this brief, Representative Henry A. Waxman has an interest in filing this brief as *amicus curiae* because the decision of the Eleventh Circuit in this case significantly distorts, and stands as an obstacle to the accomplishment of, the policies underlying legislation that he sponsored to facilitate competition in the market for prescription drugs.[1]

REASONS FOR GRANTING THE WRIT

This Court should grant the Federal Trade Commission's petition for certiorari because of the importance of the issue it presents concerning the Commission's authority to take action against anti-competitive agreements between brand-name and generic drug manufacturers that result in the withholding of generic drugs from the market. Such agreements are antithetical to the policies behind both the Hatch-Waxman Act and its 2003 amendments, which were designed to speed the introduction of generic competitors to brand-name drugs. In concluding that settlement agreements under which generic manufacturers are paid to keep their drugs off the market have pro-competitive justifications, the Eleventh Circuit turned the policies of the underlying federal legislation on their head. Although agreements such as those involved in this case may be an unfortunate, unintended consequence of the Hatch-Waxman Act, the Act was never intended to foster such agreements. The Act's intention was to promote competition by generic drug manufacturers, not to permit them to exact a portion of a brand-name manufacturer's monopoly profits in return for withholding entry into the market.

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[1] This brief was not authored in whole or in part by counsel for a party. No person or entity other than *amicus curiae* or his counsel made a monetary contribution to preparation or submission of this brief.

I. The Hatch-Waxman Act Was Intended to Protect Consumers Against Excessive Drug Costs by Enhancing Competition Between Name-Brand and Generic Drug Manufacturers.

The escalating cost of health care in the United States—and, in particular, of prescription drugs—is an enormous, nationwide problem. As the Government Accountability Office recently reported: "Prescription drug spending as a share of national health expenditures increased from 5.8 percent in 1993 to 10.7 percent in 2003 and was the fastest growing segment of health care expenditures." Government Accountability Office, *PRESCRIPTION DRUGS: Price Trends for Frequently Used Brand and Generic Drugs from 2000 through 2004* 1 (Aug. 2005) ("*GAO Study*"), at www.gao.gov/new.items/d05779.pdf. The GAO's analysis of the prices of 96 of the most commonly used prescription drugs showed that average prices for a one-month supply increased by 24.5% between January 2000 and December 2004. *Id.* at 7. The annual rate of increase was nearly double that of consumer prices generally over the same period. *Id.* Rising drug prices have become a matter of even more urgent concern to the federal government since the enactment in 2003 of the Medicare prescription drug benefit.

Brand-name drugs, many of which claim patent protection, account for most of the increase in drug costs. Generic drugs—chemically and pharmacologically identical but lacking the brand-name—are typically much less costly, on average about half the price of comparable brand-name drugs. Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* 9 (2002), at www.ftc.gov/os/2002/07/genericdrugstudy.pdf. The GAO found, for example, that the price of brand-name drugs in its sample increased by 28.9% over the five-year period covered by its study, while the price of the generic drugs surveyed increased by an average of only 9.4% over the same time. *GAO Study* at 4. The annual rate of increase for the generic drugs was

significantly less than the overall inflation rate for consumer goods, which was approximately 2.5% annually, *id.* at 7, meaning that the generic drugs studied actually *declined* in price in real terms. The tremendous savings associated with generic drugs are illustrated by the fact that, in 2001, generic drug spending accounted for only $11 billion of the approximately $130 billion spent on prescription drugs, yet that $11 billion "bought 45 percent of the total prescription drugs purchased in 2001." 149 Cong. Rec. S8187 (June 19, 2003) (statement of Sen. Kohl).

The Hatch-Waxman Act, enacted in 1984, was an early attempt to address the problem of prescription drug prices by encouraging competition against brand-name drugs from generic drug manufacturers. The legislation established a procedure whereby a generic drug manufacturer could obtain accelerated FDA approval of a drug by filing an "abbreviated new drug application," or ANDA, and demonstrating the drug's equivalence to an already-approved name-brand drug. 21 U.S.C. § 355(j). Moreover, the generic manufacturer could obtain permission to begin marketing a drug within the term of an existing patent by certifying either that the patent was invalid or that it would not be infringed by manufacture of the generic. *Id.* § 355(j)(2)(A)(vii)(IV). The legislation further encouraged introduction of generic versions of patented drugs by granting the first generic manufacturer to file a challenge to a patent on a name-brand drug a 180-day period of marketing exclusivity for the generic drug, beginning on the earlier of the first day of commercial marketing, or the date of a judicial decision holding the patent on the drug to be invalid or not infringed. *Id.* § 355(j)(5)(B)(iv).

Of course, the Act did not abrogate the patent rights of manufacturers of name-brand drugs. Rather, it sought to speed resolution of disputes over the validity and scope of drug patents by requiring a company filing an ANDA to give notice to the patent-holder, and by providing a 45-day period within which the patent-holder could obtain a 30-month stay

of the FDA's approval of the ANDA if it filed a patent infringement action against the generic manufacturer. *Id.* §§ 355(j)(2)(B) & (j)(5)(B)(iii). The Act further required that any such infringement action be expedited. *Id.* § 355(j)(5)(B)(iii). Absent an infringement action, the Act directed the FDA to approve a proper ANDA within 180 days of filing, with the approval effective immediately. *Id.* § 355(j)(5)(A).

The Act contained other provisions aimed at encouraging innovation in the development of prescription drugs by granting an extended term to drug patents to take into account delays in FDA approval that otherwise could cut into the value of a patent on a drug, *see* 35 U.S.C. § 156, and by granting innovative new drugs periods of market exclusivity during which no generic drugs could be approved, *see* 21 U.S.C. §§ 355(c)(3)(D) & (j)(4)(D). The Act thus sought to achieve a careful balance between its objectives of protecting legitimate patent rights and encouraging generic competition. *See* 130 Cong. Rec. 24425 (Sept. 6, 1984) (statement of Rep. Waxman) (describing "fundamental balance of the bill").

Notwithstanding the Act's concern for legitimate patent rights, the purpose of its provisions concerning generic drugs was clear: "to make available more low cost generic drugs by establishing a generic drug approval process for pioneer drugs first approved after 1962." H.R. Rep. No. 98-857, Pt. 1, at 14 (June 21, 1984). The Act reflected the concern that then-existing FDA procedures, which required generic drug manufacturers to complete the lengthy procedures for new drug approval once patents protecting the name-brand drug expired, "had serious anti-competitive effects," the result of which was "the practical extension of the monopoly position of the patent holder beyond the expiration of the patent." H.R. Rep. No. 98-857, Pt. 2, at 4 (Aug. 1, 1984). The ANDA procedure, which speeded approval for generics that were equivalent to approved drugs, sought to combat these anti-competitive effects and to "implement the policy objective of